

(1) *Chickens*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Aid in the treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 1 to 5 days as sole source of drinking water; treated chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 0.25 gram per gallon.

(ii) *Indications for use.* For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) *Limitations.* As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated: mix fresh solution daily;

medication must be withheld from animals 48 hours prior to slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997; 68 FR 24879, May 9, 2003]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 522.23 Acepromazine maleate injection.
- 522.44 Sterile sodium acetazolamide.
- 522.46 Alfaprostol.
- 522.56 Amikacin sulfate injection.
- 522.62 Aminopentamide hydrogen sulfate injection.
- 522.82 Aminopropazine fumarate sterile solution injection.
- 522.84 Beta-aminopropionitrile fumarate.
- 522.88 Sterile amoxicillin trihydrate for suspension.
- 522.90 Ampicillin implantation and injectible dosage forms.
- 522.90a Ampicillin trihydrate sterile suspension.
- 522.90b Ampicillin trihydrate for sterile suspension.
- 522.90c Ampicillin sodium for aqueous injection.
- 522.144 Arsenamide sodium aqueous injection.
- 522.147 Atipamezole hydrochloride.
- 522.150 Azaperone injection.
- 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.
- 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.
- 522.204 Boldenone undecylenate injection.
- 522.234 Butamisole hydrochloride.
- 522.246 Butorphanol tartrate injection.
- 522.275 N-Butylscopolammonium bromide.
- 522.311 Carfentanil citrate injection.
- 522.312 Carprofen.
- 522.313 Ceftiofur sodium powder for injection.
- 522.314 Ceftiofur hydrochloride.
- 522.315 Ceftiofur crystalline free acid.
- 522.380 Chloral hydrate, pentoobarbital, and magnesium sulfate sterile aqueous solution.
- 522.390 Chloramphenicol injection.
- 522.460 Cloprostetol sodium.
- 522.468 Colistimethate sodium powder for injection.
- 522.480 Repository corticotropin injection.
- 522.518 Cupric glycinate injection.
- 522.522 Danofloxacin.
- 522.533 Deslorelin acetate.
- 522.535 Desoxycorticosterone pivalate.
- 522.536 Detomidine hydrochloride injection.
- 522.540 Dexamethasone injection.

Food and Drug Administration, HHS**Pt. 522**

- 522.542 Dexamethasone-21-isonicotinate suspension.
522.563 Diatrizoate meglumine and diatrizoate sodium injection.
522.575 Diazepam injection.
522.650 Dihydrostreptomycin sulfate injection.
522.690 Dinoprost solution.
522.723 Diprenorphine hydrochloride injection.
522.770 Doramectin.
522.775 Doxapram hydrochloride injection.
522.778 Doxycycline hyolate.
522.784 Doxylamine succinate injection.
522.800 Droperidol and fentanyl citrate injection.
522.812 Enrofloxacin solution.
522.820 Erythromycin injection.
522.840 Estradiol.
522.841 Estradiol benzoate.
522.842 Estradiol benzoate and testosterone propionate.
522.850 Estradiol valerate and norgestomet in combination.
522.863 Ethylisobutrazine hydrochloride injection.
522.883 Etorphine hydrochloride injection.
522.900 Euthanasia solution.
522.914 Fenprastalene solution.
522.940 Colloidal ferric oxide injection.
522.955 Florfenicol.
522.960 Flumethasone implantation or injectable dosage forms.
522.960a Flumethasone suspension.
522.960b Flumethasone acetate injection.
522.960c Flumethasone solution.
522.970 Flunixin.
522.995 Fluprostenol sodium injection.
522.1002 Follicle stimulating hormone.
522.1004 Fomepizole.
522.1010 Furosemide.
522.1020 Gelatin solution.
522.1044 Gentamicin sulfate injection.
522.1055 Gleptoferron injection.
522.1066 Glycopyrrolate injection.
522.1077 Gonadorelin injectable.
522.1078 Gonadorelin diacetate tetrahydrate.
522.1079 Serum gonadotropin and chorionic gonadotropin.
522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
522.1085 Guafenesin sterile powder.
522.1086 Guaifenesin injection.
522.1125 Hemoglobin glutamer-200 (bovine).
522.1145 Hyaluronate sodium injection.
522.1150 Hydrochlorothiazide injection.
522.1155 Imidocarb dipropionate sterile powder.
522.1156 Imidocarb dipropionate solution.
522.1160 Insulin.
522.1182 Iron dextran complex injection.
522.1183 Iron hydrogenated dextran injection.
522.1192 Ivermectin injection.
522.1193 Ivermectin and clorsulon injection.
522.1204 Kanamycin sulfate injection.
- 522.1222 Ketamine hydrochloride injectable dosage forms.
522.1222a Ketamine.
522.1222b Ketamine hydrochloride with promazine hydrochloride and aminopentamide hydrogen sulfate injection.
522.1225 Ketoprofen solution.
522.1228 [Reserved]
522.1244 Levamisole phosphate injection.
522.1260 Lincomycin.
522.1289 Lufenuron suspension.
522.1290 Luprostiol sterile solution.
522.1335 Medetomidine hydrochloride injection.
522.1350 Melatonin implant.
522.1362 Melarsomine dihydrochloride for injection.
522.1367 Meloxicam.
522.1372 Mepivacaine hydrochloride injection.
522.1380 Methocarbamol injection.
522.1410 Sterile methylprednisolone acetate suspension.
522.1451 Moxidectin.
522.1452 Nalorphine hydrochloride injection.
522.1462 Naloxone hydrochloride injection.
522.1465 Naltrexone hydrochloride injection.
522.1468 Naproxen for injection.
522.1484 Neomycin sulfate sterile solution.
522.1503 Neostigmine methylsulfate injection.
522.1610 Oleate sodium solution.
522.1620 Orgotein for injection.
522.1642 Oxymorphone hydrochloride injection.
522.1660 Oxytetracycline injectable solutions.
522.1660a Oxytetracycline injection, 200 milligram/milliliter.
522.1660b Oxytetracycline injection, 300 milligram/milliliter.
522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
522.1662a Oxytetracycline hydrochloride injection.
522.1662b Oxytetracycline hydrochloride with lidocaine injection.
522.1680 Oxytocin injection.
522.1696 Penicillin G procaine implantation and injectable dosage forms.
522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.
522.1696b Penicillin G procaine aqueous suspension.
522.1696c Penicillin G procaine in oil.
522.1698 Pentazocine lactate injection.
522.1704 Sodium pentobarbital injection.
522.1720 Phenylbutazone injection.
522.1820 Pituitary luteinizing hormone for injection.
522.1850 Polysulfated glycosaminoglycan.
522.1862 Sterile pralidoxime chloride.
522.1870 Praziquantel injectable solution.
522.1881 Sterile prednisolone acetate aqueous suspension.
522.1883 Prednisolone sodium phosphate.

§ 522.23

522.1884 Prednisolone sodium succinate injection.
522.1885 Prednisolone tertiary butylacetate suspension.
522.1890 Sterile prednisone suspension.
522.1920 Prochlorperazine, isopropamide for injection.
522.1940 Progesterone and estradiol benzoate.
522.1962 Promazine hydrochloride.
522.2002 Propiopromazine hydrochloride injection.
522.2005 Propofol injection.
522.2012 Prostalene solution.
522.2063 Pyrilamine maleate injection.
522.2076 Romifidine.
522.2100 Selenium, vitamin E injection.
522.2112 Sometribove zinc suspension.
522.2120 Spectinomycin dihydrochloride injection.
522.2121 Spectinomycin sulfate solution.
522.2150 Stanozolol sterile suspension.
522.2200 Sulfachlorpyridazine.
522.2220 Sulfadimethoxine injection.
522.2240 Sulfathoxypyridazine.
522.2260 Sulfamethazine injectable solution.
522.2340 Sulfomyxin.
522.2404 Thialbarbitone sodium for injection.
522.2424 Sodium thiamilal for injection.
522.2444 Sodium thiopental implantation or injectable dosage forms.
522.2444a Sodium thiopental for injection.
522.2444b Sodium thiopental, sodium pentobarbital for injection.
522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
522.2471 Tilmicosin.
522.2474 Tolazoline hydrochloride injection.
522.2476 Trenbolone acetate.
522.2477 Trenbolone acetate and estradiol.
522.2478 Trenbolone acetate and estradiol benzoate.
522.2483 Sterile triamcinolone acetonide suspension.
522.2582 Triflupromazine hydrochloride injection.
522.2610 Trimethoprim and sulfadiazine sterile suspension.
522.2615 Tripelennamine hydrochloride injection.
522.2640 Tylosin injectable dosage forms.
522.2640a Tylosin injection.
522.2662 Xylazine.
522.2670 Yohimbine injectable.
522.2680 Zeranol.
522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

21 CFR Ch. I (4-1-05 Edition)

§ 522.23 Acepromazine maleate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.

(b) *Conditions of use.* See No. 000010, 000856 and 059130 in § 510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) *Conditions of use.* See No. 000010 in § 510.600(c) of this chapter for use in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 68 FR 33856, June 6, 2003; 69 FR 33840, June 17, 2004]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may